

REMARKS**Status of the Claims**

Claims 1-20 are currently pending in the present application. Claims have been amended. No new matter has been added. In light of the remarks herein, reconsideration of claims 1-20 is respectfully requested.

Amendments to the Claims

Claims 6, 8-9 and 16-17 have been amended. No new matter has been added.

Claim 6 has been amended to recite “comprising a daily dose of about 0.1 to 20 mg of substantially purified lutein, and at least one of the group consisting of substantially purified beta-carotene, and lycopene in amounts sufficient to act synergistically with lutein.” Support for the amendments can be found throughout the application as filed and, for example, in original claim 1.

Claim 8 has been amended to recite “synergistic combination comprises about 0.1 to 20 mg lutein, and at least one of the group consisting of beta-carotene and lycopene.” Support for the amendments to claim 8 can also be found in original claim 1. Claim 9 has been amended in light of the amendments to claim 8.

Claim 16 has been amended to recite “the synergistic combination comprises about 0.1 to 20 mg lutein, and at least one of the group consisting of beta-carotene and lycopene.” Support for the amendment to claim 16 can be found in original claim 1. Claim 17 has been amended in light of the amendments to claim 16.

Novelty of the Pending Claims

Claims 1-3, 5-10, 13 and 15-18 stand rejected under 35 U.S.C. 102(b) as being anticipated by Babish et al. (US Pub. No. 2002/0110604 A1). Applicant respectfully disagrees.

Babish is purportedly directed to a formulation of a single carotenoid species and a second component. The carotenoid species is *a member* selected from the group consisting of

astaxanthin, beta-carotene, lutein, lycopene, zeaxanthin, and cantaxanthin. The second component is selected from lipoic acid, dihydrolipoic acid (DHLA), a stilbene species, ergothioneine, a flavone species, a triterpene species, and ascorbic acid. Nowhere in Babish is there a teaching or a suggestion for a composition comprising multiple carotenoids, let alone, a synergistic combination of *about 0.1 to 20 mg lutein*, and *at least one* of beta-carotene and lycopene, as in claim 1.

Babish teaches that astaxanthin, beta-carotene, lutein, lycopene, zeaxanthin, and cantaxanthin are carotenoid species. However, Babish preferred carotenoid species is astaxanthin. (See paragraph [0024] of Babish's specification.) Moreover, Babish has no appreciation for the use of *about 0.1 to 20 mg lutein* or synergistic effects of combining *lutein* with beta-carotene and/or lycopene. In fact, none of the examples of Babish demonstrate the use of lutein in the formulation, let alone a synergistic combination of *about 0.1 to 20 mg lutein* with another carotenoid.

Therefore Babish can not anticipate claim 1, a composition comprising *about 0.1 to 20 mg lutein*, and *at least one* of beta-carotene and lycopene, claim 8, administering *about 0.1 to 20 mg lutein*, and *at least one* of beta-carotene and lycopene for decreasing oxidative damage, or claim 16, administering *about 0.1 to 20 mg lutein*, and *at least one* of beta-carotene and lycopene for reducing effects of aging.

Claims 1, 8 and 16 or dependent claims 2-3, 5-7, 9-10, 13, 15 and 17-18 are novel and patentable in light of Babish. Applicants respectfully request reconsideration and withdrawal of the anticipation rejection.

Nonobviousness of the Pending Claims

Claims 1-20 stand rejected under 35 U.S.C. 103(b) as being unpatentable over Babish et al. (US Pub. No. 2002/0110604 A1) in view of Auweter et al. (US Pub. No. 2002/0044991). Applicant respectfully disagrees.

Babish is described above. The Office Action further cites Auweter as teaching two active compounds. Auweter is cited as teaching dry powder preparations of beta-carotene,

lycopene and lutein. However, there remains no reason why one of ordinary skill in the art would combine the two references other than *a priori* knowledge of the Applicants' invention.

Babish provides no examples whatsoever of a composition comprising lutein, let alone a synergistic combination of *about 0.1 to 20 mg lutein* and *at least one* of beta-carotene and lycopene. The only experimental results demonstrate the use of astaxanthin and no teaching or suggestion to add *about 0.1 to 20 mg lutein*, and *at least one* of beta-carotene and lycopene. Auweter also provides no teachings or suggestions to a synergistic combination of *about 0.1 to 20 mg lutein* with beta-carotene and/or lycopene. Therefore, one of ordinary skill in the art would not reconstruct the claimed invention with knowledge of Babish and/or Auweter.

Furthermore, one of ordinary skill in the art would have no reason to combine Auweter with Babish, as none of the benefits described by Auweter are lacking in Babish. Auweter is concerned with encapsulating various vitamins and carotenoids to improve their stability. However, Babish utilizes a commercial preparation of astaxanthin and describes no problems with stability, bioavailability or the formation of aggregates -- the benefits taught by Auweter's composition.

Since Babish does not teach or suggest the use of a synergistic combination of lutein with beta-carotene and/or lycopene, one of ordinary skill in the art would have no reason to look to Auweter. The only reason provided by the Office Action is that the references teach all the components of the claimed invention. It appears that the Office Action is simply picking and choosing features from various pieces of art and combining them in an attempt to arrive at the claimed invention.

In order to satisfy the burden of obviousness in light of combination, it is not enough to pick and choose features from various pieces of art and just combine them to arrive at the claimed invention without any support for making such combinations. (*In re Fine*, 837 F.2d 1071, 1075, 5 USPQ2d 1596 (Fed. Cir. 1988).) As explained in *KSR International Co. v. Teleflex, Inc.*, "rejections on obviousness cannot be sustained with mere conclusory statements; instead, there *must be some articulated reasoning with some rational underpinning* to support the legal conclusion of obviousness." (MPEP § 2142, citing *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006); emphasis added; *see also* MPEP § 2143.01.)

Furthermore, the Board must guard against impermissible hindsight obtained from the knowledge of the invention of the present application and the Examiner may not “use the claimed invention as an instruction manual or ‘template’ to piece together the teachings of the prior art so that the claimed invention is rendered obvious.” (*In re Kotzab*, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000) (citation omitted).)

As there is no valid reason to combine the references other than the Applicants invention and the combination does not render the claimed invention obvious, claims 1-20 are patentable over Babish and Auweter. Applicants respectfully request reconsideration and withdrawal of the obviousness rejection.

CONCLUSIONS

In summary, reconsideration and allowance are respectfully requested for the present application. In the event that the amendments and remarks do not place this case in condition for allowance, an interview with the Examiner and his supervisor is requested prior to the issuance of a final Office Action. The Examiner is invited to call the undersigned at the telephone number below so that a personal or telephonic interview can be scheduled if there are any remaining questions regarding patentability.

Applicant also hereby petitions under 37 CFR 1.136(a) for a one month extension of time or for as many months as are required to ensure that the above-identified application does not become abandoned.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 141449, under Order No. 108341-28.

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Respectfully submitted,

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